

Dipentum® 500 mg Tablets

(olsalazine sodium)

2819
20.02.26(6)

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Dipentum 500 mg Tablets will be called Dipentum.

What is in this leaflet:

1. What Dipentum is and what it is used for
2. What you need to know before you take Dipentum
3. How to take Dipentum
4. Possible side effects
5. How to store Dipentum
6. Content of the pack and further information

1. WHAT DIPENTUM IS AND WHAT IT IS USED FOR

Dipentum belongs to a group of medicines called aminosalicylates. Dipentum works by reducing pain and swelling (inflammation) in the intestine. It reduces the actions of substances in the body that cause inflammation.

Dipentum is used to treat an inflammation of your large intestine (colon) called ulcerative colitis. It is used for short-term (acute) attacks (called "flare-ups"), and at a lower dose to maintain the improvement (maintenance treatment) and keep away further "flare-ups".

If untreated, a severe attack of ulcerative colitis may cause death due to dehydration and bursting of the colon (peritonitis).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIPENTUM

Do not take Dipentum:

- if you are allergic to olsalazine sodium or any of the other ingredients in this medicine (listed in section 6)
- if you have ever had an allergic reaction to any salicylates (e.g. aspirin and aspirin-containing products, including those bought over the counter)
- if you have severe kidney disease

If any of the above apply to you talk to your doctor or pharmacist.

Warning and Precautions

Before you start taking Dipentum your doctor will do a blood test. This will be repeated every three months for the first year, every six months for the next four years and then once a year. This is to see how well your liver and kidneys are functioning.

You should also check for signs of worsening of allergies such as asthma.

Tell your doctor immediately if you develop unexplained bruising or bleeding accompanied with fever, dizziness, sore throat and mouth ulcers. You could have developed a blood disorder.

Children and adolescents

Do not take Olsalazine Sodium tablets if you are under 12 years of age.

Other medicines and Olsalazine Sodium tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might have taken any of the following medicines:

- Aspirin or any other aspirin-containing medicines or salicylates
- Other drugs to treat ulcerative colitis
- Blood thinning agents such as warfarin or heparin or heparinoids
- Drugs that treat irritable bowel syndrome and cancer such as thioguanine and 6 mercaptopurine
- If you have recently had chickenpox vaccination (taking Dipentum may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Dipentum with food and drink

Always take Dipentum with a glass of water **after** food.

Pregnancy, breast-feeding and fertility

If you are pregnant, or trying to become pregnant or breastfeeding, talk to your doctor before taking Dipentum.

Driving and using machines

If you experience dizziness and/or blurred vision whilst taking Dipentum, do not drive or use machinery.

3. HOW TO TAKE DIPENTUM

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember: Your medicine should always be taken **after** food.

Adults, children over 12 and the elderly

Acute flare-ups

- The usual starting dose is two tablets a day (one in the morning, one in the evening at the end of a meal).
- Your doctor may increase your dose until your condition improves.
- You must not take more than six tablets a day or more than two tablets at a time.
- If a "flare-up" is severe you are likely to be given additional medicines.

Maintenance treatment

- Once the "flare-up" is controlled your doctor may gradually reduce your dose to one tablet twice a day (one in the morning, one in the evening at the end of a meal).
- This is to prevent further "flare-ups"
- You may remain on this treatment, provided it remains effective, for a long period of time.

If you take more Dipentum than you should

Do not take more Dipentum than you should. If you have taken too much, immediately go to the nearest hospital casualty department or your doctor. Take your tablets and this leaflet with you.

Signs of taking too much Dipentum include nausea, vomiting and diarrhoea.

If you forget to take Dipentum

Do not take a double dose to make up for a forgotten dose. If you forget a dose take the next one as usual.

If you stop taking Dipentum

Do not stop taking Dipentum without first talking to your doctor even if your symptoms have improved.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

Information about the ingredients

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per tablet.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms (the frequency of these side effects is unknown):

- Swelling of face, lips, tongue or throat which may cause difficulty in swallowing/breathing
- Blood disorders (reduced number of blood cells) where you could have the following symptoms: bruise or bleed easily, have a persistent sore throat, mouth ulcers, dizziness and feeling tired and feverish
- Pancreatitis where you could have the following symptoms: severe stomach pain, fever, feeling sick/being sick
- Liver disease where you could have the following symptoms: feeling sick/being sick, loss of appetite, feeling generally unwell, itching and the whites of the eyes may become yellow.

Other possible side effects:

Common: affects less than 1 in 10 people

- Headache
- Diarrhoea. It does not usually last very long, but taking your medicine at the end of a meal helps to reduce diarrhoea.
- Feeling sick
- Rash
- Joint pain

Uncommon: affects less than 1 in 100 people

- Fever
- Being sick
- Indigestion
- Raised liver enzymes (tests your doctor may perform will show changed liver function)
- Itching and/or hives, a nettle-like rash
- Unusual hair loss
- Light sensitivity.
- Increased heart rate
- Shortness of breath

- Muscle pain
- Pins and needles
- Depression
- Dizziness

Not known: frequency cannot be estimated from the available data:

- Altered breakdown of blood cells in the liver which could result in jaundice (yellowing of skin/eyes)
- Stomach pain
- Inflammation of heart muscle
- Awareness of your heartbeat
- Inflammation of sac around heart muscle
- Pain in passing urine or blood in the urine
- Difficulty in breathing
- Blurred vision
- Loss of touch sensation/numbness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIPENTUM

Keep out of the sight and reach of children.

Do not use Dipentum after the expiry date on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in a dry place.

Medicines should not be disposed of via wastewater or household waste.

Return any medicine you no longer need to your pharmacist.

If your tablets show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENT OF THE PACK AND FURTHER INFORMATION

What Dipentum contains

Dipentum contain the active substance olsalazine sodium.

Each tablet contains 500 mg olsalazine sodium.

The other ingredients are:

magnesium stearate, colloidal silicon dioxide, polyvidone K30, crospovidone and ethanol.

What Dipentum looks like

Dipentum are yellow, capsule-shaped tablets debossed with 'D500' on one side and scored on the other side.

Dipentum comes in plastic bottles containing 60 tablets.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Dipentum is manufactured by

Waymade plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR. UK.

Coripharma ehf, Reykjavikurvegur 78, IS-220 Hafnarfjörður, Iceland.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

Repackaged by Servipharm Ltd.

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Olsalazine Sodium 500 mg Tablets

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- In this leaflet, Olsalazine Sodium 500 mg Tablets will be called Olsalazine Sodium Tablets.

What is in this leaflet:

1. What Olsalazine Sodium Tablets is and what it is for
2. What you need to know before you take Olsalazine Sodium Tablets
3. How to take Olsalazine Sodium Tablets
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5. How to store Olsalazine Sodium Tablets
6. Content of the pack and further information

1. WHAT OLSALAZINE SODIUM TABLETS IS AND WHAT IT IS USED FOR

Olsalazine Sodium belongs to a group of medicines called aminosalicylates. Olsalazine Sodium Tablets works by reducing pain and swelling (inflammation) in the intestine. It reduces the actions of substances in the body that cause inflammation.

Olsalazine Sodium Tablets is used to treat an inflammation of your large intestine (colon) called ulcerative colitis. It is used for short-term (acute) attacks (called "flare-ups"), and at a lower dose to maintain the improvement (maintenance treatment) and keep away further "flare-ups".

If untreated, a severe attack of ulcerative colitis may cause death due to dehydration and bursting of the colon (peritonitis).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OLSALAZINE SODIUM TABLETS

Do not take Olsalazine Sodium:

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- if you have ever had an allergic reaction to any salicylates (e.g. aspirin and aspirin-containing products, including those bought over the counter)
- if you have severe kidney disease

If any of the above apply to you talk to your doctor or pharmacist.

Warning and Precautions

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Children and adolescents

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Other medicines and Olsalazine Sodium tablets

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- If you have recently had chickenpox vaccination (taking Olsalazine Sodium Tablets may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Olsalazine Sodium Tablets with food and drink

Always take Olsalazine Sodium Tablets with a glass of water **after** food.

Pregnancy, breast-feeding and fertility

If you are pregnant, or trying to become pregnant or breastfeeding, talk to your doctor before taking Olsalazine Sodium Tablets.

Driving and using machines

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Coripharma ehf, Reykjavikurvegur 78, IS-220 Hafnarfjörður, Iceland.

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